

Description of Baseline Characteristics Module

- Table of demographic and baseline data for the entire trial population and for each arm or comparison group
- Accommodates different data types:
 - Continuous: measure of central tendency (e.g., mean) and measure of dispersion (e.g., standard deviation)
 - Categorical: for each category (1) a count or (2) measure of central tendency and measure of dispersion

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Table 1. Baseline characteristics of the modif B alone or combined with fluconazole in the meningitis.			
	AmB	AmB+Fluc400	AmB+Fluc800
Variable	(n = 46)	(n = 48)	(n = 41)
Country			
Thailand	32 (69.6)	34 (70.8)	31 (75.6)
United States	14 (30.4)	14 (29.2)	10 (24.4)
Age, mean years ± SD	36.5 ± 8.52	36.4 ± 8.69	35.8 ± 9.36
Sex			
Male	30 (65.2)	31 (64.6)	26 (63.4)
Female	16 (34.8)	17 (35.4)	15 (36.6)
Race			
Asian/Thai	32 (69.6)	34 (70.8)	31 (75.6)
Black	8 (17.4)	10 (20.8)	3 (7.3)
White	4 (8.7)	4 (8.3)	6 (14.6)
Other	2 (4.4)	0	1 (2.4)
CD4+ T cell count, median cells/mm ³ (range)	18 (1-123)	17 (0-80)	15 (0-94)
Viral load, median copies/mL (range)	272,000 (400-1,342,580)	369,000 (50-1,000,000)	169,000 (216-1,000,000
>250 mm CSF	00 (47.0)	00 /54 0	22 (53.7)
<250 mm CSF <250 mm CSF	22 (47.8)	26 (54.2) 19 (39.6)	17 (41.5)
≈250 mm CSF Not done	20 (43.5) 4 (8.7)	3 (6.3)	2 (4.9)
CSF cryptococcal antigen titer, median (range)	2048 (4-32768)	1024 (4-71024)	2 (4.9) 1024 (4–16384)
MMSE, mean score ± SD	2048 (4-32768) 25.5 ± 5.21	25.3 ± 5.07	23.4 ± 7.25
Received prestudy fluconazole and/or flucytosine ^a	20.0 ± 0.21	20.0 ± 0.07	20.4 ± 7.20
Yes	6 (13.0)	4 (8.3)	2 (4.9)
No	40 (87.0)	44 (91.7)	39 (95.1)
Receipt of antiretroviral therapy	40 (07.0)		00 (00.1)
Yes	5 (10.9)	3 (6.2)	3 (7,3)
No	41 (89.1)	45 (93.8)	38 (92.7)
			© 2009 Infectious Dise

inicalTria	als.gov	Form	at	
Baseline Measures				
	AmphoB Standard	AmphoB+Fluc400	AmphoB + Fluc800	Total
Number of Participants [units: participants]	45	47	49	141
Age [units: participants]				
<=18 years	0	0	1	1
Between 18 and 65 years	45	47	47	139
>=65 years	0	0	1	1
Age [units: years] Mean ± Standard Deviation	37.1 ± 8.47	36.5 ± 8.21	35.9 ± 9.44	36.5 ± 8.69
Gender [units: participants]	"Default" Re	quired Measu	ures	
Female	16	15	18	49
Male	29	32	31	92
Region of Enrollment [units: participants]				
United States	14	14	14	42
Thailand	31	33	35	99

	eline Measures		
Hormonal Receptor Status (units: Participants]			
Positive	1348	1346	2694
Negative	301	303	604
Karnofsky Performance Status at Baseline units: Participants]			
80 - Activity with effort; some signs of disease	36	33	69
90 - Normal activity; minor signs of disease	315	323	638
100 - Normal no complaints; no evidence of disease	1298	1293	2591
Menopausal status junits: Participants]			
Pre-Menopausal or Other age < 50 Years	866	863	1729
Post-Menopausal or Other age > 50 Years	783	786	1569
Number of Positive Lymph Nodes units: Participants]			
[0]	0	1	1
[1 to 3]	1010	1005	2015
[4 to 10]	462	456	918
> 10	177	187	364

Bas Age	seline	Cha	racte	eristi	cs Te	empl	ate	
	Arm/Group Title *		•		•		•	
Arm	/Group Description ①							
Overall Number of E	Baseline Participants *		•		•		•	
Age, Categorical (2)		Number	Deutleleante	Number of Destining to		Number of Pastisiants		
Unit of Measure Participants		Number of	f Participants	Number of Participants		Number of Participants		
	<=18 years		(*)	r) (*)		1		
	Between 18 and 65 years	(*)		[*]		n		
	>=65 years	Measure Type [*]	[*] Dispersion/	Measure Type	[*] Dispersion/	Measure Type	(*) Dispersion/	
Age, Continuous (-	(Circle One) Mean Median Least Squares Mean Geometric Mean Log Mean	Precision Type [*] (Circle One) Standard Deviation Inter-quartile Range Full Range		Precision Type		Precision Type	
Unit of Measure	[*	(*)	3(*)	[*]	3 [*]	(*)	3[*]	
Age, Customized	2	(Circle One) Number Mean Median Least Squares Mean Geometric Mean Log Mean	Dispersion/ Precision Type [*] (Circle One) Not Applicable@ Standard Deviation Inter-quartile Range Full Range	Measure Type	Dispersion/ Precision Type	Measure Type	Dispersion/ Precision Type	
Category Title(5)	[*]	[*]	3(*)	[*]	③[*]	(*)	3[*	
Category Title (5)	[*]	(*)	3(*)	[*]	③[*]	[*]	3[*]	

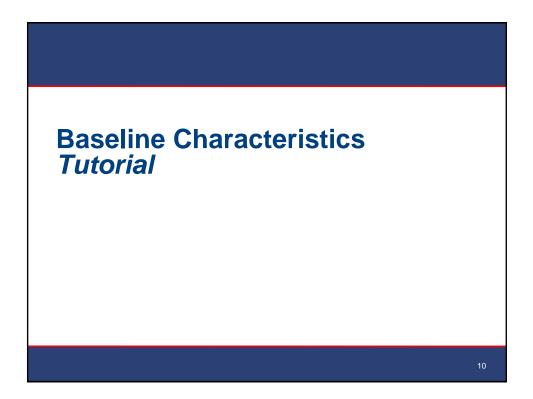
Baseline Characteristics Template Study Specific Measure

Study Specific Bas	eline Measure Title						[*]	
Baseline Measure	Description							
	Arm/Group Title*		•				•	
Ar	Arm/Group Description ①							
Overall Number	Overall Number of Baseline Participants*				•		•	
Unit of Measure	[*]	Measure Type [*] (Circle One) Number Mean Median Least Squares Mean Geometric Mean Log Mean	Dispersion/ Precision Type [*] (Circle One) (2) Not Applicable Standard Deviation Inter-quartile Range Full Range	Measure Type	Dispersion/ Precision Type	Measure Type	Dispersion/ Precision Type	
Category Title ④	[*]	[*]	(3[*]	[*]	(3)[*]	(*)	3[*]	
Category Title ④	[*]	(*)	3(*)	[*]	3[*]	(*)	3[*]	
							8	

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- Minimum requirements
 Age and Gender
- Region of Enrollment
- Other relevant demographic characteristics
- Clinical measures relevant to study, such as
 - Clinical characteristics, including baseline values of outcome measures
 - Prior and concurrent treatment characteristics



	Pos	t Bas	seline	Ch	arac	teristic	s	
Results Po	Overview Dint of Contact nple Parallel Study D	Certain Agreements	s Participant Flow	Baseline	Outcome Measure	Limitations and Caveats ID: FDXAR -no results	Adverse Events	
Edit Proto	col Delete Results	Preview Results						_
<u>Edit</u>		Name/Official Title: Organization: Phone: Email:					Expand All	1
		ERROR : Results Po	none nor Email was entered for int of Contact Name/Official Ti int of Contact Organization has	itle has not been	entered.			
<u>Edit</u>	Agreements:		I Investigator and Sponsor not spo		s not been answered.			
<u>Edit</u> Preview	Participant Flow:		Overall Study				Expand Section	
	Characteristics:	-	ntics ent will be pre-filled from protoco nces] Baseline Measures have n		Baseline Characteristic	s are first posted.		
<u>Edit</u> Preview	Outcome Measures:			ne in Pain on the	11-point Short Pain Sc	ale (SPS-11) at Week 24 [Week 24]		
		2 Secondary Not Outcome	Posted Number of Patients Safety Issue? Unk		or Greater Reduction i	n Pain as Determined by SPS-11 at Wee	k 12 [Week 12]	
		3 Secondary Not Outcome	Posted Number of Patients Safety Issue? Unk		or Greater Reduction i	n Pain as Determined by SPS-11 at Wee	k 24 [Week 24]	
		4 Secondary Not Outcome	Posted Patient's Overall Pain Safety Issue? Unit		at Week 24 [Week 24]			
			rrences] Outcome Safety Issue? nces] At least one Primary Outc			ta.		
<u>Edit</u>	Limitations and Caveats:							
		Post Adverse Events						
		ERROR : [1 occurren	nces] Adverse Events have not l	been entered.				

	Baseline	Overviev	w		
Resu	tts				
Resu	ts Point of Contact Certain Agreements	Participant Flow Baseline O		Limitations and Caveats	Adverse Events
Title:	Example Parallel Study Design*****		ID: FDXAR	-no results	
Resul	s Overview Preview Baseline				
	Add Baseline Measure	Add Arm/Group			
		Remuverol Participants received Removero	Placebo Participants received Removero Nodry Dutes	Total	
<u>Edit</u>	Overall Number of Baseline Participants	101	99	200 (Calculated)	
-	Age Categorical (Units: participants				
~	Modify Delete	Removeral	Planaho	Total	
<u>Edit</u>	<=18 years	Kemuseroi	Pille400	(Calculated)	
	Between 18 and 65 years			(Calculated)	
	>=65 years			(Calculated)	
		ERROR : [9 occurrences] A Baseline Measure Numl	eer or Central Tendency Value has not been		
	Add Baseline Measure				
	Age Continuous [Units: years]				
Edit	SOUCH ANNU	Remuverol	Placebo	Total	
		±	*	*	
		ERROR : [3 occurrences] A Baseline Measure Num ERROR : [3 occurrences] A Baseline Measure Dispe	er or Central Tendency Value has not been rsion Value has not been entered.	entered.	
	Add Baseline Measure				
	Gender, Male/Female [Units: participants]				
Edit		Remaverol	Placebo	Total	
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		ERROR : [6 occurrences] A Baseline Measure Numl	er or Central Tendency Value has not been	entered.	
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	Region of Enrollment (Units: participants]				
Edit		Remuserol	Placebo	Total	
	United States			(Calculated)	
	Mexico			(Calculated)	
	Canada			(Calculated)	
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`itle: Example Par	rallel Study Design	n****		ID: FDX	AR -no results	
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		elect "Not Applic	able" if the Measure Type is "	Number". Plea	ase do NOT select "No	t Applicable"
<u>Measure</u> Measure of Dispo		r measure types. blicable 🔹				

Results Results Point of	Certain	Deuticinent	Baseline	Outcome	Limitations and	Adverse
Contact	Agreements	Participant Flow	Delete Baseline Measure		Caveats	Events
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			Age Categorical			
You have indicate Study Design***		delete a baseline	e measure from the results porti	ion of the trial	whose title is Examp	le Parallel
Study Design***	**		e measure from the results porti		whose title is Examp	le Parallel
Study Design*** Such a deletion is	** permanent. If you	are really sure, c				le Parallel

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Results Point of Contact	Certain Agreements	Participant Flow	Baseline Baseline Overview	and the second	Limitations and Caveats	Adverse Events
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	Base	elir	ne Meas	ure			
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			101		99		200 (Ca	llculated)	
	Age Continuous Remuverol [Units: years] Participants received Remuvero		vero	Placebo Participants received Remuvero			otal		
			34.78 (9.	72.)		35.34 (10.71)	34.98 (9.89)	

Resul	lesults							
Result Conta	ts Point of ct	Certain Agreements	Participant Flow	Baseli Baseline O		Outcome Measure	Limitations and Caveats	Adverse Events
Title: E	Example Para	allel Study Design	****			ID: FDXA	R -no results	
Results	s Overview	Preview Base	line					
\langle	Add Baseline Measure		Add Arm/Group					
			Remuverol Participants received Remuvero <u>Modify:Delete</u>		Placebo Participants received Remuvero <u>Modify/Delete</u>		Total	
	Overall Num Participants	ber of Baseline	101			99	200 (Calculated)	
	Age Continu	ous [Units: years]						
Edit			Remuve	erol	Placebo		Total	
			34.78±	9.72		35.34 ± 10.71	34.98 ± 9.89	

Add Baseline Measure Results Add Baseline Measure Outcome Measure Limitations and Caveats Adverse Events Results Point of Contact Certain Agreements Participant Flow Title: Example Parallel Study Design***** ID: FDXAR -no results Baseline Measure Title:* Study Specific Characteristic • Study-Specific Baseline If the Baseline Measure Title is "Study-Specific", please enter a brief descriptive name for the measure. Measure Title: Quebec Task Force Classification of Spina Baseline Measure Additional information such as details about the collection method or participant population, if different from Overall Number of Description: Baseline Participants. Current length: 141 [Maximum allowed content length: 600] Quebec Task Force (QTF) Classification of Spinal Disorders consists of 8 classes ranging from Class 0 (no pain) to Class 7 (spinal <u>stenosis</u>). Measure Type:* Number Measure of Dispersion:* Please select "Not Applicable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other measure types. Not Applicable Unit of Measure:* If the Measure Type is "Number", the Unit of Measure is typically "participants". participants OK Cancel 20

Baseline Measure								
Conta	Its Point of C	Certain Agreements Study Design**			aseline 1e Measure		Limitations an Caveats AR -no results	nd Adverse Events
Baseli	ne Overview Create Categorie		c Characteristic [Que			-		
	Overall Number 0. Baseline Participan Study Spe Character [Quebec Task F Classificatio Spinal Disord [Units: partici	nts cific istic ^{Part} orce on of lers]	101 Remuverol icipants received Remuvero	2	-	99 lacebo received Remuvero		200 (Calculated) =sum across Arm/Groups)
<u>Edit</u>		Numbe	ROR : A Baseline Me: r or Central Tendenc as not been entered.	asure 🕻 cy N	umber or C	A Baseline Meas entral Tendency been entered.	(Calculated)	
	Total (=sum cate	across (Calculat gories)	ed)	(Calculated)		(Calculated)	21

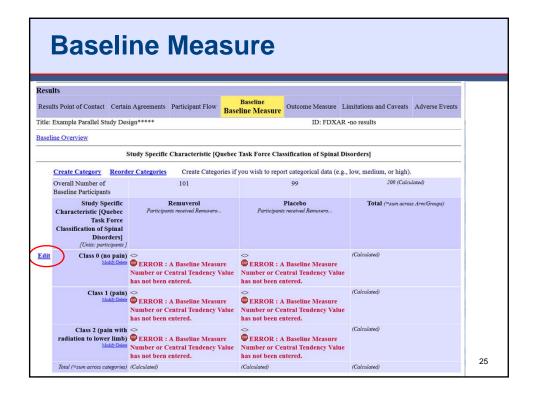
Add Baseline Measure Category

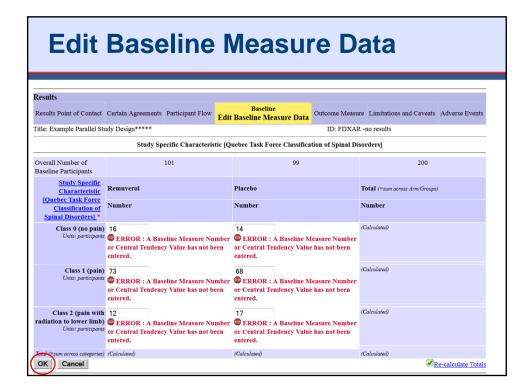
Results						
Results Point of Contact	Certain Agreements	Participant Flow	Baseline Add Baseline Measure Category	Outcome Measure	Limitations and Caveats	Adverse Events
Title: Exam	ple Parallel Stud	y Design****	** II	: FDXAR -n	o results	
	Study Spe	cific Characte	eristic [Quebec Task Force Classificati	on of Spinal	Disorders]	
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screen. Category Ti <u>Cat</u> <u>New Cat</u>	tle is required O egory Title* C egory Title* C	NLY when rep lass 0 (no pai	porting categorical data (i.e., more than o			

	Baseline Meas		ure					
Resu	lts							
Resul	Its Point of Contact Certa	in Agreements	Participant Flow	Base Baseline		Outcome Measure	Limitations and Caveats	Adverse Events
Title: I	Example Parallel Study D	esign****				ID: FDXA	R -no results	
Baseli	ne Overview							
		Study Specific	Characteristic [Q	uebec Task	Force Clas	sification of Spinal	Disorders]	
$\boldsymbol{\zeta}$	Create Category Deor	der Categories	Create Catego	ries if you w	vish to repor	rt categorical data (e	.g., low, medium, or high)	
	Overall Number of Baseline Participants	mber of 101		99			200 (Calci	ulated)
	Study Specific Characteristic [Quebec Task Force Classification of Spinal Disorders] [(Units: participants]		Remuverol nts received Remuvero.	,	Placebo Participants received Remuvero		Total (=sum acro	ss Arm/Groups)
<u>Edit</u>	Class 0 (no pair Modify Dele	ERROR :	A Baseline Measu Central Tendency V entered.			(Calculated)		
	Class 1 (pair Modify:Deld	ERROR :	A Baseline Measu Central Tendency V entered.	alue Nun		Baseline Measure atral Tendency Valu	(Calculated)	
	Total (=sum across categorie	(Calculated)		(Calc	ulated)		(Calculated)	

Add Baseline Measure Category

Results Point of Contact Certain Agreements Participant Flow Baseline Add Baseline Measure Category Outcome Measure Limitations and Caveats Adverse Events Title: Example Parallel Study Design***** ID: FDXAR -no results ID: FDXAR -no results ID: FDXAR -no results Study Specific Characteristic [Quebec Task Force Classification of Spinal Disorders] Please enter category titles and click "OK". If more categories are needed, please click "Create Category" on the next screen. Category Title is required ONLY when reporting categorical data (i.e., more than one category or row of data per measure). Category Title* Class 0 (no pain) Class 1 (pain) New Category Title* Class 1 (pain) Class 2 (pain with radiation to lower limb) OK Category Title Verse Verse	greements allel Study Des Study Spec	Flow sign****	Add Baseline Measure	I	Measure	Caveats	
Study Specific Characteristic [Quebec Task Force Classification of Spinal Disorders] Please enter category titles and click "OK". If more categories are needed, please click "Create Category" on the next screen. Category Title is required ONLY when reporting categorical data (i.e., more than one category or row of data per measure). Category Title* Class 0 (no pain) Category Title* Class 1 (pain) New Category Title* Class 2 (pain with radiation to lower limb)	Study Spec		eristic [Quebec Task Force (104 D.N. D.	D: FDXAR -n	o results	
Please enter category titles and click "OK". If more categories are needed, please click "Create Category" on the next screen. Category Title is required ONLY when reporting categorical data (i.e., more than one category or row of data per measure). Category Title* Class 0 (no pain) Class 1 (pain) New Category Title* Class 2 (pain with radiation to lower limb)		cific Characte	eristic [Quebec Task Force (Classificatio			
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New Category Title* Class 2 (pain with radiation to lower limb)	v Title* Class	s 0 (no pain)					
	v Title* Class	s 1 (pain)					
OK Cancel	v Title* Class	s 2 (pain with	radiation to lower limb)				
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E	Baseli	ne	Meas	SU	ure						
tesu	lts										
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						Placebo received Remuvero		rross Arm/Groups)			
Edit	Class 0 (no pair Modify/Del				14		30 (Calculated)				
	Class 1 (pair Modify/Del				68		141 (Calculated)				
	Class 2 (pain with radiation to low lim <u>Modify Del</u>	er D)			17		29 (Calculated)				
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Baseline		Over	view	V					
Resul	lts								
Resul Conta	ts Point of act	Certain Agreements	Participant Flow	Baselin Baseline Ov		Outcome Measure		nitations and veats	Adverse Events
Title: I	Example Para	llel Study Design	1****			ID: FDXA	AR -I	no results	
Result	s Overview	Preview Base	line						
	Add Baseline Measure		Add Arm/Grou	<u>p</u>					
			Remuv Participants receiv Modify/D	ed Remuvero	Participar	Placebo nts received Remuver Modify/Delete	ю	Total	
	Overall Numt Participants	per of Baseline	101			99		200 (Calculated)	
	Age Continue	ous [Units: years]							
Edit			Remuverol		Placebo			Total	
			34.78±	9.72		35.34 ± 10.71		34.98 ± 9.89	

